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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/686,517

10/16/2003

Amar Lulla

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26694

7590

02/02/2007

VENABLE LLP

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EXAMINER

KIM, VICKIE Y

ART UNIT

PAPER NUMBER

1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

02/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/686,517

Applicant(s)

LULLA ET AL.

Examiner

Vickie Kim

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) See Continuation Sheet is/are pending in the application.
- 4a) Of the above claim(s) 46-48, 52-60 and 67-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8, 10-12, 14, 15, 17-20, 22, 23, 25, 26, 28, 29, 31-33, 35-40, 44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 90/503843.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 9/2004 & 10/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

**Continuation of Disposition of Claims: Claims pending in the application are 1-4,6,8,10-12,14,15,17-20,22,23,25,26,28,29,31-33,35-40,44-48,52-60 and 67-73.**

## **DETAILED ACTION**

### ***Election acknowledged***

1. Applicants' election the invention of group I, claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, 44-45 is acknowledged. The restriction is made without traverse. Therefore, the restriction requirement is deemed to be proper and made FINAL.

2. The claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, 44-48, 52-56, 57-60 and 67-73 are pending and the elected claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, 44-45 are presented for the examination. All remaining claims not drawn to the elected invention are withdrawn from further consideration as being non-elected. The following rejections are made.

### ***Information Disclosure Statement(IDS)***

The information disclosure statement (IDS) is submitted on 9/8/2004 and 10/16/2003. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner. Please refer to applicants' copy of the 1449 submitted herewith.

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. Claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, 44-45 are rejected under 35 U.S.C. 102 (b) as anticipated by Osipow et al(US 4328319).

The claims are drawn to a spray composition for topical application comprising;

- (i) at least one medicament(0.0001-30% );
- (ii) at least on vehicle; and
- (iii) at least one component selected from the group
  - at least one permeation enhancer;
  - at least one solubilizer;
  - at least one plasticizer; and
  - at least one water soluble additive.

Osipow et al(US'319, hereinafter) teaches a propellant composition containing a active ingredient(e.g. drug), a film forming synthetic polymer, vehicle(e.g. water) and other carriers, wherein the composition is made into the final products useful for medicament for external application, e.g. topical or rectal, etc.), see abstract and col.11, lines 57 –col. 12, lines 38.

As to the claims 2-3, 12, 14-15, 17-19, 37-39 which are further limiting medicament, all the critical elements required by the claims are well taught by US'319. US'319 teaches various medicaments such as steroids and hormones(hydrocortisone or testosterones) at col. 12, lines 1-38 and the effective amount of medicament present from 0.02 to 15% .

As to the claims 4, 31-32, 37, 40 and 45 which further limit film former, US'319 teaches film forming polymers (e.g. alkyl acrylate and alkyl methacrylate polymers and

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copolymers or ethyl cellulose), where the composition contains the said polymers upto 50% by weight, see col 8, lines 54-col.9, lines 20 and lines 64-66.

As to the claims 6, 8, 10-11, 20, 22-23, 28-29, 33, 35-37, 40, 44, US'319 teaches all the critical elements required by the claims, for example, permeation enhancer(e.g. surfactants or oleic acid, 0.0001-8%) at col. 7, lines 5-31; plasticizer(e.g. citrate esters such as tributyl citrate, 0.0001-10%) at col. 10, lines 60 to col. 11, lines 11; propylene glycol(humectant), water(vehicle), sodium lauryl sulphate(solubilizer) at col. 8, lines 15-32 and col 7, lines 6, lines 55-69.

As to the claims 25-26 which further limit propellant, US'319 teaches propellant (20-70%) such as P114, P22 at col 9, lines 20-67 and col. 10, lines 3-7.

All the critical elements are well taught and thus, the claims are anticipated by the cited reference.

It is noted that the limitations(e.g. stable, breathable film upon application) found in preamble is inherently possessed by the product taught by US'319. If the prior art structure is capable of performing the intended use, then it meets the claim.

Since all the components are substantially same and the structure of the composition is well anticipated, the recitation should be inherently possessed by the product of US'319. It is also noted that the term used in cited reference may not be same, however, the compounds(actual ingredients) used to formulate the composition are same and thus, all the functions related to the terms(e.g. humectant, solubilizer, etc) included in claims are naturally possessed and essentially achieved by the composition of cited reference of the record.

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Thus, all the claims are properly included in this rejection.

### ***Double Patenting***

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-4, 6, 8, 10-12, 14-15, 17-20, 22-23, 25-26, 28-29, 31-33, 35-40, 44-45 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6962691. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of claims found in US'691 patent which are drawn to an aerosol spray composition for topical application comprising medicament(e.g. estradiol), film former(e.g. povidone), permeation enhancer(e.g. menthol), solubilizer(vit. E),

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plasticizer(e.g. dimethylisosorbide), water soluble additive(e.g. ethanol), and propellant(e.g. trichloromonfluoromethane), have embraced by the scope of the claimed subject matter found in instant application since both patent and instant application are drawn to substantially same invention with almost same ingredients as mentioned above in 102 rejection. Thus, the instant claims are not patentably distinct over the patented reference(US'691) and subject to double patenting rejection.

### ***Conclusion***

1. No claim is allowed.
2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 571-272-0579. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should



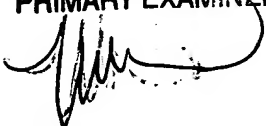
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you have questions on access to the Private PAIR system, contact the Electronic  
Business Center (EBC) at 866-217-9197 (toll-free).

**VICKIE KIM**  
**PRIMARY EXAMINER**

A handwritten signature in black ink, appearing to read 'Vickie Kim', written over a horizontal line.

Vickie Kim  
January 31, 2007  
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